

# Hepatitis B

## (Acute, Chronic, Perinatal)

All hepatitis B cases should be reported.

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### 1) THE DISEASE AND ITS EPIDEMIOLOGY

#### A. Etiologic Agent

The hepatitis B virus (HBV) is a DNA hepadnavirus. Infection results in production of measurable antibody to hepatitis B surface antigen (HBsAg), hepatitis B core antigen (HBcAg), and hepatitis B e antigen (HBeAg).

#### B. Clinical Description and Laboratory Diagnosis

Infection with HBV may result in **acute** or **chronic** disease, both of which can be asymptomatic. If symptoms are present, onset of **acute** disease is usually insidious with loss of appetite, vague abdominal discomfort, nausea, vomiting and sometimes arthralgias and rash, often progressing to jaundice. Fever may be absent or low-grade. Liver enzyme levels are markedly elevated. Severity ranges from inapparent cases (detectable only by liver function tests) to fulminant, fatal cases. The case-fatality rate in hospitalized patients is about 1%. Disease tends to be worse and mortality higher in those over 40 years old. As with hepatitis A, asymptomatic infections are common in children less than 10 years of age. Approximately 30% to 50% of older children, adolescents and adults have asymptomatic infections.

The risk of **chronic** infection decreases with age at infection. As many as 90% of infants infected at birth (perinatal) develop chronic HBV infection, compared to an average of 30% of children infected between 1 and 5 years of age and 2–6% of those acquiring infection as older children or adults. Chronically infected persons are at increased risk for developing chronic liver disease (e.g., cirrhosis or chronic hepatitis) or liver cancer (primary hepatocellular carcinoma) later in life. Approximately 25% of those infected during early childhood will ultimately die at an early age from the complications of cirrhosis and liver cancer.

The laboratory confirmation is based upon demonstration of specific antigens and/or antibodies in patient's sera or liver biopsies. Laboratory diagnosis is established when IgM antibody to HBV core antigen (anti-HBc) is positive (if done) or when HBsAg is positive and IgM antibody to hepatitis A virus (anti-HAV) is negative (if done). Three clinically useful antigen-antibody systems are: HBsAg and antibody to HBsAg (anti-HBs or HBsAb); HBcAg and antibody to HBcAg (anti-HBc or HBcAb); and HBeAg and antibody to HBeAg (anti-HBe or HBeAb). See Table 1 for more information.

#### C. Reservoirs

Humans are the only natural hosts.

#### D. Modes of Transmission

HBV is transmitted through blood or body fluids via a parenteral or permucosal (mucous membrane) exposure. The highest concentrations of the virus are in blood and serous fluids; lower titers are found in semen and even lower titers in saliva.

Some examples of parenteral exposures are needle sticks, sharing or reusing nonsterile needles or syringes, transfusion of blood and blood products (rare in the U.S. due to current blood donor screening and testing protocols), hemodialysis, acupuncture, and tattooing. The most common permucosal exposures are through perinatal transmission from an infected mother to her infant at birth (vertical transmission) and sexual

(heterosexual and homosexual) activity (horizontal transmission). Per mucosal exposures also occur in laboratories and healthcare settings, contributing to horizontal transmission in facilities and communities.

Person-to-person spread of HBV can occur in settings involving interpersonal contact over extended periods, such as when a chronically infected person resides in a household. In household settings, nonsexual transmission occurs primarily from child to child, and young children are at highest risk for infection. The precise mechanisms of transmission from child to child are unknown; however, frequent interpersonal contact of nonintact skin or mucous membranes with blood-containing secretions or perhaps saliva are the most likely means of transmission. Transmission from sharing objects, such as wash cloths, towels, or toothbrushes, also can occur because HBV can survive at ambient temperatures in the environment for days and even weeks. Fecal-oral transmission does not appear to occur. Approximately one-third of infected persons do not have a readily identifiable risk factor.

#### **E. Incubation Period**

The incubation period of HBV infection is an average of 60 to 90 days, with a range of 45 to 160 days, and may be occasionally as long as 6 to 9 months.

#### **F. Period of Communicability or Infectious Period**

A person is considered infectious as long as HBsAg is detectable in the blood. Most people are infectious from 1 to 2 months before to 1 to 2 months after the onset of symptoms. Persons who have **chronic hepatitis B** (known as **carriers**) remain infectious indefinitely. Persons with acute and chronic hepatitis B with circulating HBeAg are more infectious than those that are HBeAg negative. Measurable levels of HBeAg are associated with higher levels of HBV replication.

#### **G. Epidemiology**

Worldwide, HBV is a major cause of chronic liver disease and liver cancer. The frequency of HBV infection and patterns of transmission vary greatly throughout the world. In most areas of the U.S., Canada, western Europe, Australia, and southern South America, the infection rate is low and occurs primarily in adolescents and adults; 5% to 8% of the total population have been infected, and 0.2% to 0.9% have a chronic infection.

Within the U.S. there are pockets of high endemicity, including first-generation immigrants from areas where HBV is endemic, Alaskan Natives and inner city groups. The highest risk of early childhood infection is among children born to mothers from HBV endemic countries. The majority of early childhood infections, however, occur among African American and white children. Before routine childhood immunization in the United States, it is estimated that approximately 33,000 children born to HBsAg-negative mothers were infected each year during their early childhood. In developed countries, populations at high risk for HBV exposure include injecting drug users, heterosexuals with multiple partners, homosexual men, residents and staff in institutions for the developmentally disabled, employees in hemodialysis centers, and people in certain healthcare and public safety occupations.

In contrast, in China, Southeast Asia, the Pacific Islands, eastern Europe, the Central Asian republics, most of the Middle East, Africa, the Amazon Basin, and some Caribbean islands, HBV infection is highly endemic, with a lifetime risk of HBV infection greater than 60%. In these areas, most infections occur in infants or children under the age of 5 years, 70% to 90% of the adult population has been infected, and 8% to 15% have a chronic infection. In the rest of the world, HBV infection is of intermediate endemicity with chronic HBV carriage occurring in 2% to 7% of the population.

## **2) REPORTING CRITERIA AND LABORATORY TESTING SERVICES**

### **A. New Jersey Department of Health and Senior Services (NJDHSS) Case Definitions**

## 1. ACUTE HEPATITIS B

### CASE CLASSIFICATION

#### a. CONFIRMED

- An acute illness with discrete onset of symptoms and jaundice or elevated serum aminotransferase, **AND** IgM antibody to hepatitis B core antigen (anti-HBc) positive (if done), **or** hepatitis B surface antigen (HBsAg) positive **and** IgM antibody to hepatitis A virus (anti-HAV) negative (if done).

#### b. PROBABLE

Not used.

#### c. POSSIBLE

Not used.

#### d. NOT A CASE

In CDRS, this denoted a chronic illness or “carrier state” and was utilized when a case was not determined to be acute but had a positive HBsAg.

## 2. PERINATAL HEPATITIS B INFECTION

### CASE CLASSIFICATION

#### a. CONFIRMED

HBsAg positivity in any infant aged  $\geq 1$ –24 months who was born in the U.S. or in U.S. territories to an HBsAg-positive mother.

#### b. PROBABLE

Not used.

#### c. POSSIBLE

Not used.

## 3. CHRONIC HEPATITIS B INFECTION

Most HBV-infected persons with chronic infection are asymptomatic. However, many have chronic liver disease, which can range from mild to severe including cirrhosis, and/or liver cancer. In CDRSS, acute and chronic hepatitis B cases have separate designations. Thus, chronic hepatitis B is no longer termed “not a case” but is designated a confirmed case of chronic hepatitis B if diagnosed in that calendar year.

### CASE CLASSIFICATION

#### a. CONFIRMED

- HBsAg positive, total anti-HBc positive and IgM anti-HBc negative  
OR
- HBsAg positive two times at least 6 months apart AND
- Diagnosed in current calendar year.

#### b. NOT A CASE

- Chronic cases of hepatitis B infection diagnosed in a prior calendar year.

## **B. Laboratory Testing Services Available**

The NJDHSS Public Health Environmental Laboratories (PHEL) do not perform routine laboratory testing for hepatitis B for screening or diagnostic purposes for the general public. Some tests are performed at no cost for patients followed in the New Jersey Perinatal Hepatitis B Prevention Project (See 3.C.3. below). Testing is generally conducted through private commercial laboratories.

## **3) DISEASE REPORTING AND CASE INVESTIGATION**

### **A. Purpose of Surveillance and Reporting**

- To identify sources/sites of transmission and to prevent spread from such sources.
- To ensure identification of infected pregnant women and prevent perinatal transmission to their babies.

### **B. Laboratory and Healthcare Provider Reporting Requirements**

The New Jersey Administrative Code (N.J.A.C. 8:57-1.8) stipulates that laboratories report (by telephone, confidential fax, over the Internet using the Communicable Disease Reporting and Surveillance System (CDRSS) or in writing) all cases of hepatitis B (including **carriers/ chronic hepatitis B cases and hepatitis B positivity in a pregnant woman**) to the local health officer having jurisdiction over the locality in which the patient lives, or, if unknown, to the health officer in whose jurisdiction the health care provider requesting the laboratory examination is located. The health care providers must report all above cases to the local health officer having jurisdiction over the locality in which the patient lives. Please refer to the lists of reportable diseases [www.state.nj.us/health/cd/njac857.pdf](http://www.state.nj.us/health/cd/njac857.pdf) for information.

### **C. Local Health Department Reporting and Follow-Up Responsibilities**

#### **1. Reporting Requirements**

The New Jersey Administrative Code (N.J.A.C. 8:57-1.8) stipulates that each local health officer must report the occurrence of any case of hepatitis B, as defined by the reporting criteria in Section 2A above. Refer to the Health Officers Reporting Timeline (<http://www.state.nj.us/health/cd/njac857.pdf>) for information on prioritization and timeliness requirements of reporting and case investigation.

#### **2. Case Investigation**

- a. It is the health officer's responsibility (or his/her designee) to investigate the case by interviewing the patient and others who may be able to provide pertinent information. If a laboratory report is received by NJDHSS, data entry of that basic information will be made into CDRSS by the state, but case investigation will be the responsibility of the local health department. If the patient address is not listed on this report, it will be sent back to the lab or healthcare provider by NJDHSS for a complete address.
- b. The investigation will usually require requesting information from the health care provider (e.g., symptomatic/asymptomatic, whether patient had elevated liver function tests). A primary objective is to determine if the patient has acute or chronic disease.
- c. Please document case findings in CDRSS. The form letter for healthcare providers (CDS-L2) <http://web.doh.state.nj.us/forms> can be utilized to obtain necessary information. Entry into CDRSS:  
Case management button: Add new case after performing person search.
  1. Patient info: Enter patient demographics and disease name (Hepatitis B) in first screen. Enter subgroup of acute or chronic if known; or mark as pending if investigation is incomplete.
  2. Other addresses: use as needed for additional addresses.
  3. Clinical status: document if known (include prior hepatitis B immunization, pregnancy status, physician name). Onset date is usually not known and can be left blank.

4. Signs/symptoms: Check appropriate boxes for signs and symptoms. Please note if physician did not provide this information. This information is critical for determination of acute status.
5. Risk factors: mark checkboxes if known. Items 2-7 may not be known until investigation has been completed.
6. Laboratory evaluation: enter appropriate lab tests and results.
7. Contact tracing: document contacts (if known).
8. Comments: Use this screen to enter general comments not covered by other sections; however, other screens also have a “comments” option.
9. Epidemiology: route of transmission can usually be determined through investigation of risk factors. Method of case detection: by receipt of a positive lab report, contact investigation, or unknown. Cases electronically entered by a laboratory will have case status initially designated as “report under investigation” and a “pending” report status.
10. Case classification: (i) Case status—designate as report under investigation (RUI), probable, possible, not a case.  
 (ii) Report status: LHD open, LHD review, LHD closed, delete or reopened. After LHD completes its report status as LHD closed, NJDHSS will review case and make final determination. Once NJDHSS assigns status as DHSS-approved, the LHD cannot change its case status. Upon review, if NJDHSS notices a missing element or has questions about the case, the case may be changed to LHD open or LHD review and a comment will be documented explaining this, with communication of same to the LHD investigator.  
 (iii) If the case is open and the investigation is incomplete, continue to investigate in a timely manner. If three unsuccessful attempts have been made to contact the physician for additional patient information, this should be documented in the Comments section of CDRSS, and the case status should be changed to **Not a Case**.  
 (iv) If the case is open or pending, the investigation is complete but the case does not meet case definition, the case status should be changed to **Not a Case**. You do not need to send paperwork to NJDHSS.  
 (v) If the case is open, the investigation is complete, and the case meets the case definition for either acute or chronic infection, then change the case status in CDRSS to LHD confirmed. Paperwork does not need to be sent to NJDHSS.  
 (vi) If new lab data is received after case closure, it only needs to be entered if it would change case status. NJDHSS would need to reopen the case for the LHD.

d. Use the following guidelines to assist in completing a case report:

If possible, record the date and time of the onset of illness and symptoms accurately to establish the incubation period for hepatitis B (6 weeks to 6 months), and determine sexual and close contacts. Some of these investigations will be quite sensitive in nature. Reassure the patient that all information is kept strictly confidential and is only obtained to determine his/her likely source of exposure and to protect others

that might be at risk. If a case is determined to be an acute infection, the following questions should be asked regarding a time period of **6 weeks to 6 months prior to illness onset**:

- Was the patient hospitalized (including day surgery)?
  - Did the patient receive intramuscular injections or intravenous infusions ?
  - Did the patient have multiple finger sticks in a nursing home?
  - Did the patient use a finger stick device at home or have a phlebotomist draw in the outpatient setting?
  - Was the patient a contact of a confirmed or suspect hepatitis B case? If yes, was contact sexual, household, or other?
  - Was the patient employed in a medical, dental or other field involving contact with human blood?
  - Did the patient have acupuncture?
  - Did the patient have an accidental needlestick injury?
  - Did the patient have any dental procedures?
  - What was the patient's sexual preference? How many sexual partners?
  - Did the patient receive a transfusion?
  - Was the patient associated with dialysis or a kidney transplant? If yes, was the case a patient or employee?
  - Did the patient use needles for injection of street drugs?
- e. Institution of disease control measures is an integral part of case investigation. It is the local health officer's responsibility to understand, and if necessary, institute the control guidelines listed below in Section 4, Controlling Further Spread.
- f. When investigating children with hepatitis B, determine their country of birth. Investigation of infants with hepatitis B (aged > 1-24 months) should include determining the HBsAg status of the mother and whether the child was born in the U.S. or U.S. territories.
- g. If the case identified occurred in a **woman of reproductive age** (11 to 50 years of age), it is important to determine and document pregnancy status. If the patient is pregnant, record the estimated date of delivery, the expected location of delivery and the name, address and phone number of the obstetrical care provider. This information will facilitate follow-up by the New Jersey Hepatitis B Prevention Project, as described below.

### 3. **Follow-up of pregnant hepatitis B carriers and their infants and families**

The NJDHSS Hepatitis B Prevention Project is responsible for coordinating activities related to the prevention of perinatal transmission of hepatitis B throughout the state. Local health departments assume the lead role in their jurisdiction for case management and timely and appropriate follow-up of vaccine doses for infants and susceptible household and sexual contacts identified in this Project. Case management involves counseling the pregnant woman and identifying, counseling, performing serologic screening, and vaccinating the susceptible household and sexual contacts; tracking the vaccine doses of the infant to ensure the vaccine is administered according to schedule and that the infant receives post-vaccination serologic testing to confirm successful therapy.

Project-funded serologic post-vaccination testing of infants and pre-vaccination testing of sexual and household contacts is available under the auspices of the Project through the NJDHSS PHEL if the family's insurance does not cover the cost of testing. Hepatitis B vaccine is also available through the Project for infants born to HBsAg positive women and their susceptible sexual and household contacts who are unable to purchase the vaccine biologics because they do not have a health care provider, or health insurance, or are seen by local health departments receiving other state provided vaccines.

The Perinatal Hepatitis B Case and Contact Report (IMM20) form is to be completed on all HBsAg positive pregnant women, the infants born to these women and their household and sexual contacts. The form is divided into three sections: “Data on Prenatal Woman” (Section I), “Data on Contact(s)” (Section II) and “Data on Newborn” (Section III). The back of the form includes instructions for completion. Contact the Vaccine Preventable Disease Program at (609) 588-7512 to obtain copies of the reporting form and the manual, New Jersey Perinatal Hepatitis B Prevention Project, which provides more specific information on the Project.

**4. Follow-up of sexual and household contacts:**

Household and sexual contacts identified through the Perinatal Hepatitis B Project staff should be counseled, screened, and if susceptible, immunized. Local health department staff can refer sexual and adult household contacts lacking health insurance or a health care provider for serologic screening to their local STD clinic with a completed lab slip and a referral.

## **4) CONTROLLING FURTHER SPREAD**

### **A. Isolation and Quarantine Requirements (N.J.A.C. 8:57-1.12)**

The current recommendations of the CDC and NJDHSS are as follows:

#### **Minimum Period of Isolation of Patient**

No restrictions except for exclusion from organ and blood donation and counseling to modify activities in order to prevent transmission.

#### **Minimum Period of Quarantine of Contacts**

High-risk contacts should receive hepatitis B immunoglobulin (HBIG) and vaccine. Infants born to infected women should also receive HBIG and vaccine.

### **B. Protection of Contacts of a Case**

**Immunization of contacts:** Products available for post-exposure prophylaxis include HBIG and hepatitis B vaccine.

**1. Infants born to HBsAg-positive mothers** should be treated as follows:

- a. Give HBIG (0.5 ml IM) and hepatitis B vaccine IM according to Table 2.
- b. Screen the infant for HBsAg and anti-HBs at 9 to 15 months or 1 month after the last dose. If HBsAg is not present and anti-HBs concentration is 10 mIU/mL or greater, the infant is protected.
- c. Infants who do not respond to the initial vaccine series (anti-HBs concentration is <10mIU/mL) and are not HBsAg-positive should be given a second 3-dose series of hepatitis B vaccine (same schedule as initial series) and re-screened at 1 to 2 months after the last dose.
- d. **Infants who become HBsAg-positive** should be referred to a pediatric hepatologist for follow-up, and the parents should be counseled. Since perinatal HBV infection is a reportable disease, the HBsAg-positive infant should be reported to the Vaccine Preventable Disease Program, Perinatal Hepatitis B Prevention Project at (609) 588-7512.

**2. Infants born to mothers whose HBsAg status is not known** should be given hepatitis B vaccine within 12 hours of birth while awaiting HBsAg test results on the mother. If the mother is determined to be

positive, the infant should receive HBIG as soon as possible, within 7 days of birth. This child should then complete the 3-dose hepatitis B vaccination series according to Table 2. Upon completion of the vaccine series, the infant should be screened for the HBsAg and anti-HBs (Section 4B, 1, b).

If the mother is determined to be **HBsAg-negative**, the infant should complete the 3-dose hepatitis B vaccine series according to the immunization schedule on Table 4.

3. **Unvaccinated infants exposed to a primary caretaker with acute hepatitis B** should receive a single dose of HBIG (0.5 mL), and the first dose of the hepatitis B vaccine series as soon as possible. Complete the vaccine series following the immunization schedule in Table 4.
4. **Sexual contacts of a person with acute hepatitis B**, if susceptible, should receive a single dose of HBIG (0.06 mL/kg), and the first dose of hepatitis B vaccine as soon as possible after exposure, and complete the vaccine series using the age appropriate vaccine dose according to the immunization schedule in Table 5.
5. **Nonsexual household contacts of a person with acute hepatitis B**, if susceptible, who have had a blood exposure to the index patient (such as sharing toothbrushes or razors) should receive a single dose of HBIG (0.06 mL/kg) and should initiate and complete the 3-dose series of hepatitis B vaccine according to Table 5. Vaccination histories should be assessed for all household contacts and unvaccinated persons should be vaccinated. Exposed persons who are in the process of being vaccinated but have not completed the vaccine series should receive a dose of HBIG and complete the series as scheduled.
6. **Household and sexual contacts of persons with chronic hepatitis B**, if susceptible, should initiate the first dose of hepatitis B at the time of their initial clinical evaluation and complete the 3-dose series of hepatitis B vaccine according to Table 5.
7. **Persons with percutaneous or mucous membrane exposures** to either an acute or chronic case, if susceptible, should receive postexposure prophylaxis according to Table 3.

## C. Managing Special Situations

### School and Daycare

The risk of transmission of HBV in school and daycare settings has always been very low. This risk is now even lower because the proportion of susceptible children is decreasing as requirements for hepatitis B immunization for entry into kindergarten/and grades 1 and 6, and high school have been implemented. To prevent the transmission of hepatitis B and other bloodborne diseases in these settings, however, the following guidelines should be followed.

**Primary prevention:** Ensure compliance with all hepatitis B immunization requirements for schools and daycare. Vaccination is also recommended for unvaccinated classmates of hepatitis B carriers who behave aggressively (e.g., biting, frequent scratching) or who have medical conditions, such as open skin lesions (e.g., generalized dermatitis or bleeding problems), that increase the risk of exposing others to infectious blood or serous secretions.

**Secondary prevention:** Persons exposed to potentially infectious blood or other body fluids should be treated according to the “Recommendations for Postexposure Prophylaxis After Percutaneous Or Permucosal Exposure to HBV” outlined in Table 3. However, in the case of a bite by a person whose hepatitis B status is unknown, it is unlikely that it will result in transmission and blood testing is not recommended for either biter or victim. The risk of HBV acquisition when a susceptible child bites an HBV carrier is not known. However, most experts would not give HBIG to the susceptible biting child who does not have oral mucosal disease when the amount of blood transferred is small.



**Notification:** Parents may wish to inform the school nurse or daycare program director about a child who is a known hepatitis B carrier to allow for proper precautions and assessment of behavior issues that could facilitate transmission. However, this is not necessary since policies and procedures to manage exposure to blood or blood-containing materials should already be established and implemented. Parents of other children attending the school/daycare **do not** need to be informed.

**Exclusions:** Adults and children ill with acute hepatitis B should stay home until they feel well, and fever and jaundice are gone. There is no reason to exclude a person with hepatitis B from employment or attendance once they have recovered from acute infection. Admission of a known hepatitis B carrier with specific risk factors, such as biting, open rashes or sores that cannot be covered or bleeding problems, should be assessed on an individual basis by the child's doctor, school/daycare and responsible public health authorities. Because these children pose a risk to others in daycare, consideration may be given to exclusion from daycare until the aggressive behavior ceases or until all contacts have been vaccinated. However, over the next few years, the proportion of children who are immunized will increase. Concern about bites and HBV transmission should also decrease over this time period.

**Prevention Guidelines:** Whether or not individual hepatitis B carriers have been identified, it is important that school staff receive regular training on the prevention of bloodborne disease. Personnel should be educated about standard precautions for handling blood or blood-containing materials. All students should receive age-appropriate instruction regarding the potential dangers of contact with other people's blood and other body fluids. Some standard precautions include:

- Follow all procedures for hand washing and cleanliness.
- Always treat all blood as potentially dangerous fluid and observe universal precautions, including using disposable gloves when cleaning or removing blood or body fluid spills.
- Do not permit sharing of personal items that may become contaminated with blood or body fluids, such as toothbrushes or eating utensils.
- Cover open skin lesions.
- Place disposable items contaminated with blood or body fluids in plastic bags in covered containers.
- Store contaminated clothing or washable items separately in plastic bag, and send them home with the owner for proper cleaning.
- Wash and sanitize surfaces of contaminated objects with a dilute solution of 1 ½ cups household bleach in 1 gallon of water (1:10 dilution) applied for at least 30 seconds, made up on a daily basis, or disinfect objects by boiling objects for 10 minutes.
- Supervise closely to discourage and prevent aggressive behavior.
- Provide age-appropriate education to adolescents and young adults about prevention of sexually transmitted diseases, including hepatitis B (e.g., safer sex, vaccination).

#### **Reported Incidence is Higher than Usual/Outbreak Suspected**

If the number of reported cases in your city/town is higher than usual, or if you suspect an outbreak, investigate clustered cases in an area or institution to determine source of infection. If evidence indicates a common source, applicable preventive or control measures should be instituted. Consult with the NJDHSS Vaccine Preventable Disease Program at (609) 588-7512 or the NJDHSS Infectious and Zoonotic Disease Program at (609) 588-7500 before the implementation of other control measures.

#### **D. Preventive Measures**

General control and prevention measures include implementing all hepatitis B immunization requirements and recommendations, as described below.

## 1. Pre-exposure Prophylaxis:

- **Infants** born to **HBsAg-negative mothers** should initiate and complete the 3-dose hepatitis B vaccine series, according Table 4.
- **Children** age (1-10) years can be vaccinated according to any of the following schedules and Table 5.

0, 1, 6 months  
0, 2, 4 months

- **Adolescents** age (11-19 years) can be vaccinated according to any of the following schedules:

0, 1, 6 months  
0, 1, 4 months  
0, 2, 4 months  
0, 12, 24 months

Adolescents (11-15 years only) may use a 2 dose scheduling option (Table 6). Administer the first dose of Recombivax HB at month 0, and the 2<sup>nd</sup> dose 4-6 months later (minimum interval between doses is 4 months). Both doses should be administered while the adolescent is 11-15 years of age, with the 2<sup>nd</sup> dose given by the 16<sup>th</sup> birthday (Table 6).

- **Adults** can be vaccinated according to any of the following schedules:

0, 1, 6 months  
0, 1, 4 months  
0, 2, 4 months  
0, 1, 2, 12 months (for persons, such as travelers, who require rapid protection)

A 3-dose hepatitis A/hepatitis B combination vaccine Twinrix<sup>TM</sup> manufactured by GlaxoSmithKline is available for use in persons 18 years of age and older. The administration schedule is month 0, 1, and 6 months.

**New Jersey public employees who are at risk of occupational exposure to blood and body fluids** should initiate and complete the 3-dose series of hepatitis B vaccine according to the schedule on Table 5. The vaccine services are the responsibility of state, and county and local municipalities for their respective at-risk employees.

**State Immunization Requirements:** Three doses of hepatitis B vaccine are required for children born on or after January 1, 1996, and entering kindergarten or grade 1 (whichever comes first) and for children born on or after January 1, 1990, and entering grade 6. Students born on or before January 1, 1990 entering, attending, or transferring into grades 9-12 are also required to receive three doses of hepatitis B vaccine.

For students entering grade 6, the alternate two dose vaccine regimen is acceptable only if administered in accordance with the Advisory Committee on Immunization Practices and FDA dosing schedules for adolescents 11-15 years of age.

Refer to the New Jersey Sanitary Code, "Immunization of Pupils in Schools", (Chapter 14), readopted with amendments July, 2004 for further information. A copy of this regulation can be obtained through the NJDHSS website at [www.state.nj.us/health/cd/chap14.htm](http://www.state.nj.us/health/cd/chap14.htm) or by contacting the Vaccine Preventable Disease Program at (609) 588-7512.

The Occupational Safety and Health Administration of the U.S. Department of Labor has issued a regulation requiring private employers of workers at risk for occupational exposure to HBV to offer HBV immunization to these employees at the employer's expense.

## ADDITIONAL INFORMATION

The NJDHSS Vaccine Preventable Disease Immunization Program has numerous written, audio and video materials targeting pregnant women, adolescents, adults and healthcare providers with information about hepatitis B. Call (609) 588-7512 for information about available materials and to contact the Perinatal Hepatitis B Project.

A Hepatitis B Fact Sheet can be obtained at the NJDHSS website at <http://www.state.nj.us/health/>. Click on the "Topics A to Z" link and scroll down to subject "Hepatitis B". Call (609) 588-7500 to contact the Hepatitis B Coordinator.

CDC's Viral Hepatitis Program website: [www.cdc.gov/ncidod/diseases/hepatitis](http://www.cdc.gov/ncidod/diseases/hepatitis)

Hepatitis B Foundation website: [www.hepb.org](http://www.hepb.org)

Immunization Action Coalition website: [www.immunize.org](http://www.immunize.org)

Hepatitis B Investigation letter, CDS-L2: <http://web.doh.state.nj.us/forms>

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## TABLES

Table 1

Marker	Abbreviation	Definition/Significance
Hepatitis B surface antigen	<b>HBsAg</b>	Indicates infectivity. Present in acutely and chronically infected persons. Persists indefinitely in <b>chronic</b> carriers.
IgG antibody to HBsAg	<b>anti-HBs or HBsAb</b>	Indicates immunity, either from past infection or vaccination.
Total, or IgG, antibody to hepatitis B core antigen (HBcAg)	<b>anti-HBc or HBcAb</b>	Indicates prior infection at some unknown time. Immunization does <b>not</b> produce anti-HBc.
IgM antibody to hepatitis B core antigen (HBcAg)	<b>IgM anti-HBc</b>	Indicates infection within the past 6 months (including in HBsAg-negative persons during the “window” phase of infection). This is the <b>best</b> test to diagnose <b>acute</b> hepatitis B.
Hepatitis B e antigen	<b>HBeAg</b>	Identification of infected persons at increased risk for transmitting HBV. Seen transiently in most infections, and persists indefinitely in <i>some</i> carriers.
Antibody to HBeAg	<b>Anti-HBe</b>	Identification of infected persons with lower risk for transmitting HBV.
Hepatitis B DNA	<b>HBV-DNA</b>	Used to assess and monitor treatment of patients with chronic HBV infection.

**Table 2**

**How to interpret common hepatitis B panel results**

<b>Tests</b>	<b>Results</b>	<b>Interpretation</b>
HBsAg Anti-HBc Anti-HBs	Negative Negative negative	Susceptible
HBsAg Anti-HBc Anti-HBs	Negative Negative Positive with $\geq 10\text{mIU/mL}^*$	Immune due to vaccination
HBsAg Anti-HBc Anti-HBs	Negative Positive positive	Immune due to natural infection
HBsAg Anti-HBc IgM anti-HBc Anti-HBs	Positive Positive Positive Negative	acutely Infected
HBsAg Anti-HBc IgM anti-HBc Anti-HBs	Positive Positive Negative Negative	Chronically Infected
HBsAg Anti-HBc Anti-HBs	Negative Positive Negative	Four Interpretations Possible+

Immunization Action Coalition: *Vaccinate Adults.*

*\*Postvaccination testing, when recommended, should be performed 1-2 months following the last dose of vaccine. Infants born to HBsAg-positive mothers should be tested at 9-15 months of age or one month after the last dose whichever happens first.*

- +1. *May be recovering from acute HBV infection.*
- 2. *May be distantly immune, but the test may not be sensitive enough to detect a very low level of Anti-HBs in serum.*
- 3. *May be susceptible with a false positive anti-HBc.*
- 4. *May be chronically infected and have an undetectable level of HBsAg present in the serum.*

**Table 3: The Immunoprophylaxis of infants born to HBsAg positive mothers**

Single-antigen vaccine <sup>1</sup>		Single-antigen <sup>1</sup> + combination vaccine <sup>2</sup>	
Dose	Age	Dose	Age
1 <sup>3</sup>	Birth (within 12 hours)	1 <sup>2,3</sup>	Birth (within 12 hours)
HBIG <sup>4</sup>	Birth (within 12 hours)	HBIG <sup>4</sup>	Birth (within 12 hours)
2	1-2 months	2 <sup>5</sup>	2 months
3	6 months <sup>6</sup>	3 <sup>5</sup>	4 months
		4 <sup>5</sup>	6 months (PEDIARIX) <sup>6</sup> or 12 – 15 months (COMVAX)

<sup>1</sup> Pediatric formulation of either RECOMBIVAX HB or ENGERIX-B

<sup>2</sup> COMVAX (combined hepatitis B-Hib conjugate vaccine) and PEDIARIX (combined hepatitis B-DTaP-IPV vaccine) cannot be administered at birth or before 6 weeks of age.

<sup>3</sup> Pediatric formulation of either RECOMBIVAX HB or ENGERIX-B can be used beginning at birth.

<sup>4</sup> Hepatitis B immunoglobulin ( 0.5.mL) given intramuscularly in a separate site from vaccine.

<sup>5</sup> PEDIARIX administered at 2, 4, 6 months of age to complete immunization against hepatitis B and primary immunization against diphtheria, tetanus, pertussis, and polio. COMVAX administered at 2, 4, and 12-15 months of age to complete immunization against both hepatitis B and *Haemophilus influenzae* type b.

<sup>6</sup> The last dose in the vaccine series should not be administered before age 24 weeks (164 days).

**Table 4**

**Recommendations for postexposure prophylaxis after percutaneous or permucosal exposure to HBV**

<b>Vaccination and antibody status of exposed person<sup>1</sup></b>	<b>Treatment</b>			
	<b>Source HBsAg-Positive</b>	<b>Source HBsAg-Negative</b>	<b>Source unknown or not tested</b>	
			<b>High Risk</b>	<b>Low Risk</b>
<b>Unvaccinated</b>	HBIG <sup>2</sup> (1 dose) and begin hepatitis B vaccine series	Begin hepatitis B vaccine series	Begin hepatitis B vaccine series	Begin hepatitis B vaccine series
<b>Previously vaccinated</b>				
<b>Known responder<sup>3</sup></b>	No treatment	No treatment	No treatment	No treatment
<b>Nonresponder<sup>3</sup></b>				
Not revaccinated <sup>4</sup>	HBIG (1dose) and begin a revaccination series	No treatment; begin a revaccination series	HBIG (1 dose) and begin a revaccination series	Begin a revaccination series
After revaccination <sup>4</sup>	HBIG (2 doses) <sup>5</sup>	No treatment	HBIG (2 doses) <sup>5</sup>	No treatment
<b>Antibody response unknown</b>	Test for anti-HBs  If adequate, <sup>3</sup> No treatment  If inadequate, HBIG x 1 and vaccine booster	No treatment	Test for anti-HBs  If adequate, <sup>3</sup> no treatment  If inadequate, give vaccine booster and check anti-HBs in 1-2 months	

<sup>1</sup> Persons known to have been infected with HBV are immune and require no treatment.

<sup>2</sup> Hepatitis B immunoglobulin (0.6 ml/kg) administered intramuscularly.

<sup>3</sup> Adequate response to anti-HBs  $\geq 10\text{mIU/mL}$  after vaccination.

<sup>4</sup> Revaccination = additional three-dose series of hepatitis B vaccine administered after the primary series.

<sup>5</sup> First dose as soon as possible after exposure and the second dose one month after the first dose.

**Table 5**  
**Immunoprophylaxis of infants born to HBsAg- negative mothers**

<b>Single-antigen vaccine<sup>1</sup></b>		<b>Birth-dose<sup>1</sup> + combination<sup>2</sup></b>		<b>Combination<sup>2</sup> without birth dose<sup>3</sup></b>	
<b>Dose</b>	<b>Age</b>	<b>Dose</b>	<b>Age</b>	<b>Dose</b>	<b>Age</b>
1 <sup>3</sup>	Birth (before discharge) <sup>4</sup>	1 <sup>3</sup>	Birth (before discharge) <sup>4</sup>	1 <sup>2</sup>	2 months <sup>4</sup>
2	1-4 months	2 <sup>2</sup>	2 months	2 <sup>2</sup>	4 months
3 <sup>5</sup>	6 – 18 months	3 <sup>2</sup>	4 months	3 <sup>2,5</sup>	6 months (PEDIARIX) OR 12- 15 months (COMVAX)
		4 <sup>2,5</sup>	6 months (PEDIARIX) or 12- 15 months (COMVAX)		

<sup>1</sup> Pediatric formulation of either RECOMBIVAX HB or ENGERIX-B

<sup>2</sup> COMVAX (combined hepatitis B-Hib conjugate vaccine) and PEDIARIX (combined hepatitis B-DTaP-IPV vaccine) cannot be administered at birth or before 6 weeks of age.

<sup>3</sup> Pediatric formulation of either RECOMBIVAX HB or ENGERIX-B can be used beginning at birth.

<sup>4</sup> The first dose can be delayed until after hospital discharge only if there is a physician's order to defer the vaccine at birth based on specific documentation of a negative HBsAg test during this pregnancy. If the first dose is not administered before hospital discharge, it should be administered by age 2 months.

<sup>5</sup> The last dose should not be administered before age 24 weeks (164 days).



**Table 6**

<b>Hepatitis B Vaccine Adolescent and Adult Schedule</b>		
Dose	Usual Interval	Minimum Interval
Primary 1	---	---
Primary 2	1 month	1 month
Primary 3	5 months	2 months
* third dose must be separated from first dose by at least 4 months		

**Table 7**

<b>Alternative Adolescent Vaccination Schedule</b>
<ul style="list-style-type: none"><li>• Two 10 mcg doses of Recombivax HB separated by 4-6 months</li><li>• May only be used for adolescents 11-15 years of age</li><li>• Only applies to Merck hepatitis B vaccine</li></ul>